



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Use of Influenza Disease Models to Quantitatively Evaluate the Benefits and Risks of Vaccines:

A Technical Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: “Use of Influenza Disease Models to Quantitatively Evaluate the Benefits and Risks of Vaccines: A Technical Workshop.” The purpose of this public workshop is to provide stakeholders a forum to discuss the design of a model to quantitatively estimate the benefits and risks of a hypothetical influenza vaccine, and to seek from a range of experts, feedback on the current version of the model used by the Center for Biologics Evaluation and Research (CBER) and suggestions for further development.

The public workshop will include presentations and panel discussions with experts from academia, regulated industry, government, and other stakeholders.

Date and Time: The public workshop will be held on August 23, 2012, from 9 a.m. to 4 p.m.

Location: The public workshop will be held at the Bethesda North Marriott Hotel & Conference Center; 5701 Marinelli Rd., Bethesda, MD, 20852; 301-822-9200.

Contact Person: Richard Forshee, Center for Biologics Evaluation and Research (HFM-210), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6042, email: Richard.Forshee@fda.hhs.gov.

Registration: Mail, fax, or email your registration information (including name, title, firm name, address, telephone, and fax numbers, and email address) to Richard Forshee (see Contact Person) by August 16, 2012. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space-available basis beginning at 8 a.m. If you need special accommodations due to a disability, please contact Richard Forshee (see Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

The workshop will provide an opportunity for discussions on the application of open source influenza infectious disease computer simulation models to generate quantitative estimates of the benefits and risks of influenza vaccination.

The public workshop presentations and panel discussions will: (1) Discuss recent developments in open-source, agent-based, publicly available computer simulation tools to model influenza and other infectious diseases; (2) discuss and seek technical feedback on the CBER quantitative model of influenza vaccine benefit/risk; and (3) discuss possible applications of quantitative benefit/risk assessment methods to vaccine assessment of quantitative benefit/risk assessment methods to vaccine assessment.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.aspx>

[ult.htm](#). Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: July 11, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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